

DEC 27 1996

**I. 510(K) SUMMARY**

**Submitted By:**

Neal E. Fearnot, President  
MED Institute, Incorporated  
P.O. Box 2402  
West Lafayette, IN 47906  
(317) 463-7537  
May 16, 1996

**Device:**

Trade Name:	Needle's Eye Snare
Common/Usual Name:	Snare, Retrieval Basket, Basket Introducer
Proposed Classification Name:	Embolectomy Catheter 21 CFR Part 870.5150 (74DXE)

**Predicate Devices:**

The Needle's Eye Snare is similar to predicate devices which are used for the intravascular retrieval of foreign bodies, and is also of similar technology in terms of material composition and method of operation.

**Device Description:**

The Needle's Eye Snare is intended for use in the percutaneous removal of indwelling catheters, cardiac leads, fragments and foreign objects. The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the Needle's Eye Snare is provided by their established history of use in medical devices manufactured by the Cook Pacemaker Corporation.

**Substantial Equivalence:**

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Pacemaker Corporation. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.